

REMARKS

The Office Action mailed May 1, 2006, has been received and reviewed. Claims 10, 11, 15 through 18, 21 through 23, 27, 29 through 32, 35 through 38, and 46 through 51 are currently pending in the application. Claims 10, 11, 15 through 18, 21 through 23, 27, 29 through 32, 35 through 38, and 46 through 51 stand rejected. Applicants have amended claims 10, 11, and 15, and respectfully request reconsideration of the application as amended herein.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 4,376,118 to Daher et al. and U.S. Patent No. 5,972,373 to Yajima et al.

Claims 10, 11, 15, and 49 through 51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Daher et al. (U.S. Patent No. 4,376,118) and Yajima et al. (U.S. Patent No. 5,972,373). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The Examiner relies on Daher as teaching a non-aqueous solution of tetracycline that includes N-methyl-2-pyrrolidone, lauryl lactate, antioxidant, polysorbate solubilizer. As acknowledged by the Examiner, Daher does not teach use of polyvinylpyrrolidone. Yajima is relied upon as teaching a composition that contains tetracycline, glycerol monolaurate or glycerol monostearate, polyvinylpyrrolidone, and polysorbate or polyoxyethylene-polyoxypropylene block copolymers. Because Daher and Yajima both contain tetracycline antibiotic, the Examiner relies on *In re Kerkhoven* for the proposition that it is obvious to combine two compositions in order to form a third composition to be used for the same purpose.

However, independent claims 10, 11, and 15 have been amended to require a stable non-aqueous viscous protein formulation comprising at least one protein, and a non-aqueous single-phase biocompatible viscous vehicle comprising a polymer consisting of polyvinylpyrrolidone, a surfactant consisting of glycerol monolaurate or polysorbate, and a solvent consisting of lauryl lactate, wherein the vehicle is adapted for use as an injectable vehicle or for use in an implantable delivery device. Therefore, there is no motivation to combine the cited references. Additionally, the combined references do not teach all of the elements of claims 10, 11, and 15, because the combined references do not contain protein. Additionally, Daher is drawn to topical tetracycline formulations and Yajima is drawn to compositions for oral administration to remove unpleasant taste from drugs.

The nonobviousness of independent claims 10, 11, and 15 precludes a rejection of claim 49-51 which depend therefrom because a dependent claim is obvious only if the independent claim from which it depends is obvious. *See In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *see also* MPEP § 2143.03. Therefore, the Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to the cited dependent claims.

In view of the foregoing, Applicants respectfully request withdrawal of the obviousness rejections based on Daher and Yajima.

35 U.S.C. § 112 Claim Rejections

35 U.S.C. § 112, First Paragraph

Claims 16 through 18, 21 through 23, 27, 29 through 32, 35 through 38, and 46 through 51 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection, as hereinafter set forth.

Specifically, the aforementioned claims were rejected on grounds that there is “no description exemplification for claim employing proteins other than human growth hormones.” (Office Action at page 4). However, the rejected claims are drawn to non-aqueous protein formulations comprising a non-aqueous single-phase biocompatible viscous vehicle having a

polymer consisting of polyvinylpyrrolidone, a surfactant consisting of glycerol monolaurate or polysorbate, and a solvent consisting of lauryl lactate. As discussed throughout the specification and as recited in the claims, the protein is incorporated into a stable, non-aqueous, single-phase biocompatible viscous vehicle that must be uniformly dispensed over an extended period of time at a low flow rate and stable at body temperature for extended periods of time. As acknowledged by the Examiner, the viscous vehicle is adequately described in the specification. Applicants contend that proteins to be incorporated into the viscous vehicle are well known in the art and, more specifically, placed in the context of the present application, the person of skill in the art would be convinced that the inventors possessed the invention. Based on the skilled artisan's knowledge of proteins and preparation of protein formulations in viscous vehicles, they are enabled to make and use the invention without undue experimentation. As held in *Falkner v. Inglis*, 79 USPQ2d 1001 (Fed. Cir. 2006):

Examples are not necessary to support adequacy of written description, provided patent specification otherwise provides sufficient information to convince person of ordinary skill in art that inventor possessed claimed invention, since specification is written for person of ordinary skill, who reads patent with knowledge of what has come before.

The parties also dispute several aspects of our law of written description, which we now address. We conclude that the Board applied correct law. Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Id. at 1007.

A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be

included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

Id. In view of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph rejection to claims 16-18, 21-23, 27, 29-32, 35-38, and 46-51.

35 U.S.C. § 112, Second Paragraph

Claims 49 through 51 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. More specifically, the limitation “wherein the ratios” was rejected as not having proper antecedent basis. Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 49-51 have been amended to recite the aforesaid limitation as “the components are in a range” and to remove the phrase “wherein the ratios”.

In view of the foregoing, Applicants believe that the Section 112 rejections have been overcome and respectfully request withdrawal of the same.

ENTRY OF AMENDMENTS

The amendments to claims 10, 11, 15, and 49-51 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search.

CONCLUSION

Claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38, and 46-51 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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